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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/657,418	09/08/2003	Archibald I. J. Brain	108195.137/LMA-018	9018

23483 7590 09/08/2005

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BOSTON, MA 02109

EXAMINER

MITCHELL, TEENA KAY

ART UNIT	PAPER NUMBER
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3743

DATE MAILED: 09/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

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<b>Office Action Summary</b>	<b>Application No.</b> 10/657,418	<b>Applicant(s)</b> BRAIN, ARCHIBALD I. J.	
	<b>Examiner</b> Teena Mitchell	<b>Art Unit</b> 3743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 08 September 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-30 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 08 September 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Information Disclosure Statement***

The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

### ***Claim Rejections - 35 USC § 102***

**The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:**

**A person shall be entitled to a patent unless –**

**(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.**

**Claims 1, 6-8, 9-13, 16, 17, 19-22, and 26-29 are rejected under 35 U.S.C. 102(b) as being anticipated by Brain (5,303,697).**

Brain in a Laryngeal mask (12) discloses: an inflatable cuff (14), the cuff defining a central opening at least when inflated, the cuff being insertable through a mouth of a patient to an inserted location within the patient (Fig. 3), the cuff surrounding a glottic opening of the patient when inflated (Fig. 3) and at the inserted location; an airway tube (10) extending from a proximal end to a distal end, the airway tube defining an internal passage, a sealed airway passage extending from the proximal end of the tube through

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the internal passage to the glottic opening when the cuff is inflated and at the inserted location (Figs. 1-4); and a tab (9) fixed to the airway tube near the proximal end of the airway tube, the tab being disposed outside of the mouth of the patient when the cuff is at the inserted location (Fig. 3), the tab extending outwardly from the airway tube in a first direction when the cuff is at the inserted location, a second direction being perpendicular to a line extending from a nose of the patient to a chin of the patient, the first direction being transverse to the second direction (Fig. 3).

With respect to claim 6, Brain discloses the tab being disposed near an upper lip of the patient when the cuff is at the inserted location (Fig. 3).

With respect to claim 7, Brain discloses the tab (9) extending from the airway tube towards a nose of the patient when the cuff is at the inserted location (Fig. 3).

With respect to claim 8, Brain discloses the tab (9) including a first portion and a second portion, the first portion of the tab extending outwardly from the airway tube, the second portion extending from the first portion at an angle with respect to the first portion, the angle being different than one hundred eighty degrees (see illustration of Fig. 1 below).

With respect to claim 9, Brain discloses a connector portion (50) and a second portion, the connector portion including a proximal portion, a distal portion, and a flange (9), the flange being disposed between the proximal and distal portions, the distal portion being inserted into a proximal end of the second portion, the proximal portion being cylindrical (Fig. 4).

With respect to claim 10, Brain discloses the flange (9) defining the tab (Fig. 4).

With respect to claim 11, Brain discloses the tab (9) with respect to the functional limitations of the tab being configured to permit application of adhesive tape to the tab and a face of the patient such that the tape, when applied, biases the tab towards the mouth of the patient, the tab (9) of Brain is fully capable of meeting the claimed functional limitations because the tab (9) of Brain can be fixed to the airway tube (10; Col. 3, lines 1-5) and therefore able to be adhesively taped to the user's face.

With respect to claim 12, note rejection of claim 11 above.

With respect to claim 13, the device of Brain is fully capable of adhesive tape, when applied, biasing a distal end of the device against an esophageal sphincter of the patient because the tape would cause movement of the tab (9) and therefore cause movement of the tube and cuff.

With respect to claim 16, Brain discloses a tab (9) including a first portion and a second portion, the first portion of the tab (9) extending outwardly from the airway tube, the second portion extending from the first portion at an angle with respect to the first portion, the angle being different than one hundred eighty degrees (See illustration of Fig. 1 below).

With respect to claim 17, Brain discloses the tab (9) being substantially rigid.

With respect to claim 19, Brain discloses the device further including an epiglottis support flange (27).

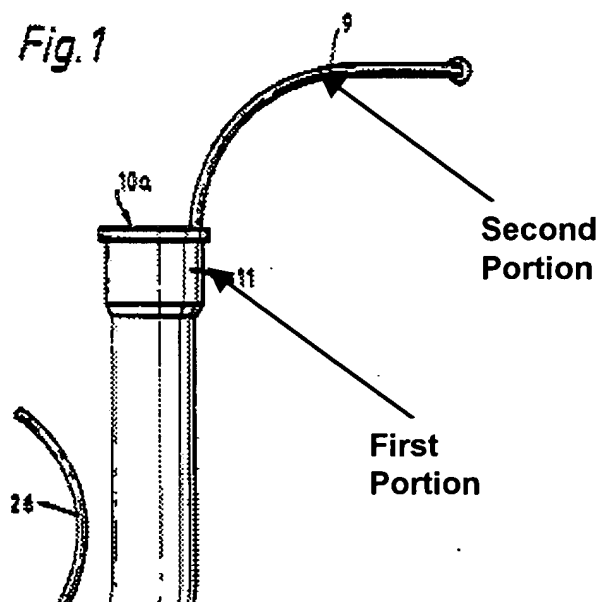
With respect to claim 20, Brain discloses the cuff (14) defining an inner perimeter that bounds the central opening, the device further including an epiglottis flange (27), the flange defining an outer perimeter of the cuff (Fig. 2) and an inner perimeter (Fig. 2),

the outer perimeter of the flange being fixed to the inner perimeter of the cuff (14), the inner perimeter of the flange being fixed to the inner perimeter of the cuff (14), the inner perimeter of the flange defining a second opening, the second opening being smaller than the central opening (Fig. 2).

With respect to claim 21, Brain discloses an inflatable cuff (14), the cuff defining a central opening at least when inflated, the cuff being insertable through a mouth of a patient to an inserted location within the patient, the cuff (14) surrounding a glottic opening of the patient when inflated and at the inserted location (Fig. 3); and an airway tube (10) extending from a proximal end to a distal end, the airway tube including a tube wall that defines an internal passage (Figs. 1-4), a sealed airway passage extending from the proximal end of the tube through the internal passage to the glottic opening when the cuff is inflated and at the inserted location (Fig. 3), the airway tube defining a tab (9), the tab being disposed outside of the mouth of the patient when the cuff (14) is at the inserted location, the tab extending outwardly from the tube wall in a first direction when the cuff is at the inserted location, a second direction being perpendicular to a line extending from a nose of the patient to a chin of the patient, the first direction being transverse to the second direction (Figs. 1-4).

With respect to claim 22, Brain discloses the tab (9) extending from the tube wall in the first direction and is fully capable of sufficiently far to permit application of adhesive tape to the tab and to a head of the patient when the cuff is at the inserted location (Fig. 3) such that the adhesive tape, when applied, biases the tab towards the head of the patient.

With respect to claim 26, Brain discloses an inflatable cuff (14), the cuff defining a central opening at least when inflated, the cuff (14) being insertable through a mouth of a patient to an inserted location within the patient, the cuff surrounding a glottic opening of the patient when inflated and at the inserted location (Fig. 3); an airway tube (10) extending from a proximal end to a distal end, the airway tube (10) defining an internal passage, a sealed airway passage extending from the proximal end of the tube through the internal passage to the glottic opening when the cuff (14) is inflated and at the inserted location (Fig. 3); a flange fixed to the airway tube (9) near the proximal end of the airway tube, the flange being disposed outside of the mouth of the patient when the cuff is at the inserted location, the flange (9) including a first portion and a second portion (see illustration of Fig. 1 below), the first portion of the flange extending in a first direction outwardly from the tube, the second portion extending from the first portion at an angle with respect to the first portion, the angle being different than one hundred eighty degrees.



With respect to claim 27, Brain discloses an airway tube (10) extending from a proximal end to a distal end, the airway tube (10) defining an internal passage; an inflatable cuff (14), the cuff defining a central opening at least when inflated, the cuff being disposed near the distal end of the airway tube (10), the cuff being insertable through a mouth of a patient to an inserted location within the patient, the cuff surrounding a glottic opening of the patient and at the inserted location (Fig. 3), a sealed passage extending from the proximal end of the tube through the internal passage to the glottic opening when the cuff is inflated and at the inserted location (Fig. 3), the cuff defining an inner perimeter that bounds the central opening (Figs. 1-4); and an epiglottis support flange (27), the flange defining an outer perimeter and an inner perimeter, the flange comprising a solid sheet of material extending between the outer and inner perimeters of the flange, the outer perimeter of the flange being fixed to the inner perimeter of the cuff, the inner perimeter of the flange defining a single opening, the single opening being smaller than the central opening (Figs. 2, 3A).

With respect to claim 28, Brain discloses the epiglottis support flange (27) being part of the cuff (14).

With respect to claim 29, Brain discloses the device further including a tab (9) fixed to the airway tube (10) near the proximal end of the airway tube (10), the tab (9) being disposed outside of the mouth of the patient when the cuff is at the inserted location, the tab extending outwardly from the airway tube in a first direction when the cuff is at the inserted location, a second direction being perpendicular to a line



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extending from a nose of the patient to a chin of the patient, the first direction being transverse to the second direction (Figs. 1-4).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 2-5, 14, 15, and 23-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brain (5,303,697).

With respect to claim 2 and the first direction extending from the patient's chin towards the patient's nose, at the time the invention was made, it would have been an obvious matter of design consideration to a person of ordinary skill in the art at the time the invention was made to have the first direction extending from the patient's chin towards the patient's nose because applicant has not disclosed that have the first direction extending from the patient's chin towards the patient's nose provides an

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advantage, or solves any particular problem. It appears that having the first direction any configuration as long as the airway tube is maintained in the inserted position the device would perform equally well. Accordingly, the use of the first direction extending from the patient's chin towards the patient's nose is deemed to be a design consideration which fails to patentably distinguish over the prior art of Brain.

With respect to claims 3-5, note rejection of claim 2 above.

With respect to claim 14, Brain does not disclose the tab extending from the airway tube for at least fifteen millimeters. However, it appears the distance of the tab from the airway tube would perform equally well with the distance at other distances especially since all users are not the same and would require different distances to accommodate different users. Accordingly, the tab extending from the airway tube for at least fifteen millimeters is deemed to a design consideration, which fails to patentably distinguish over the prior art of Brain.

With respect to claim 15, note rejection of claim 14 above.

With respect to claims 23-25 the claimed method steps would have been obvious because they would have resulted from the use of the device of Brain as noted above with respect to claims 1, 8, 11-13, and 21 above.

**Claims 18 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brain (5,303,697) in view of Frankel (4,793,327).**

With respect to claim 18, Brain does not disclose the cross section of the airway tube being oblong. Frankel in an airway tube teaches an oblong cross-section airway tube providing a means so that the tube more truly fits the shape of the esophagus (Col.

3, lines 59-68). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the tube of Brain to have a cross-section of the tube be oblong doing so would have provided a tube so that it will more truly fit the shape of the esophagus including the oblong cross-section taught by Frankel.

With respect to claim 30, note rejection of claim 18 above.

### ***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The balance of art is cited to show airway tubes: 2003/0131845; 6,427,686; 5,865,176; 5,878,745; 5,896,858; 5,791,341; 5,623,921; 5,682,880; 5,771,889; 5,277,178; 5,297,547.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Teena Mitchell whose telephone number is (571) 272-4798. The examiner can normally be reached on Monday-Friday however the examiner is on a flexible schedule.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry Bennett can be reached on (571) 272-4791. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Teena Mitchell  
Primary Examiner  
Art Unit 3743  
August 30, 2005

*TKM*  
TKM